**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| INTEGRA LIFESCIENCES CORP., INTEGRA LIFESCIENCES SALES LLC, CONFLUENT SURGICAL, INC., AND INCEPT LLC,<br><br>Plaintiffs,<br><br>v.<br><br>HYPERBRANCH MEDICAL TECHNOLOGY, INC.,<br><br>Defendant. | C.A. No. 15-819-LPS-CJB<br><br>**[EXHIBITS 4, 8, AND 9 FILED SEPARATELY UNDER SEAL]** |

**PLAINTIFFS' LETTER BRIEF IN OPPOSITION TO HYPERBRANCH MEDICAL TECHNOLOGY, INC.'S MOTION TO STRIKE PLAINTIFFS' IDENTIFICATION OF EVIDENCE REGARDING PRIORITY DATES AND BIOCOMPATIBILITY THEORY [D.I. 375]**

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Dear Judge Burke:

Defendant wrongly complains about opinions by Plaintiffs' experts that are entirely proper and timely. In rendering their opinions, Plaintiffs' experts relied on the very same fact discovery which Defendant had in its possession. Defendant's motion to strike is a baseless attempt to remove the damaging rebuttal opinions which vitiate Defendant's prior art invalidity defenses.

Nearly a year ago, Plaintiffs supplemented their responses to Defendant's Interrogatory Nos. 1 and 2 pursuant to Court Order. Specifically, the Court ruled in open court on December 1, 2016: "I'm going to require that the plaintiff provide supplemental responses to Defendant's interrogatories Number 1 and 2, and in doing so, to specify in those responses the individuals who contributed to the conception and the asserted priority dates for the claims on a claim-by-claim basis." (Ex. 1 at 17, lines 6-11) (emphasis added). On December 9, 2016, Plaintiffs complied with the Court's Order by providing supplemental interrogatory responses that specified: (1) the individuals who contributed to the conception; and (2) the asserted priority dates for Asserted Claims on a claim-by-claim basis. (*See* Ex. 2 at 9-13; 15-16). Plaintiffs also indicated in their supplemental responses that they intended to rely upon the effective filing dates listed on the face of the Asserted Patents, and Plaintiffs identified where supporting evidence for such priority dates could be found. (Ex. 2 at 15-16). Moreover, because the interrogatories called for expert testimony, Plaintiffs informed Defendant that Plaintiffs would provide additional information during expert discovery in accordance with the Court's Scheduling Order. (*See* Ex. 2 at 7, 13, and 15). No additional motion to compel was ever filed by Defendant. The Court's December 1, 2016 Order correctly did not require Plaintiffs to reveal prematurely any expert opinions interpreting the claims and the teachings of the priority documents with respect to the asserted priority dates. This was the job of Plaintiffs' expert Dr. Mays pursuant to the Scheduling Order for disclosure of opinions, after Defendant's expert Dr. Lowman revealed the prior art invalidity positions in his opening expert report.

The facts are undisputed. Plaintiffs provided Defendant with the patents-in-suit and their priority applications so Defendant and Dr. Lowman could investigate the asserted priority dates well before Dr. Lowman selected prior art for his opening report. Defendant even deposed the individuals who contributed to conception and had every opportunity to ask about priority dates for the claims of the patents-in-suit. Based on the priority dates disclosed by Plaintiffs and the production of the priority documents, Dr. Lowman (with the assistance of counsel) was well prepared to investigate and select prior art, i.e., references that were actually prior art, as part of a well-informed litigation strategy. Dr. Lowman no doubt undertook this analysis when assisting in the preparation of over 3800 pages of Final Invalidity Contentions. However, as evidenced by his reply report, Dr. Lowman could not successfully rebut Dr. Mays' priority analysis, and so the baseless motion to strike soon followed. It is simply not credible that both Dr. Lowman and Defendant's many litigation counsels simply and stubbornly put their heads in the sand with respect to Plaintiffs' priority allegations and priority documents produced during fact discovery. It is inconceivable that over *3800 pages* of Final Invalidity Contentions could have been prepared without Defendant analyzing whether the prior art was actually prior art in view of the fact discovery produced by Plaintiffs.

Over a year ago, Plaintiffs objected to Interrogatory No. 3 on the basis that it called for expert testimony. (*See* Ex. 3 at 11-12). Plaintiffs informed Defendant that Plaintiffs would provide information in response to Interrogatory No. 3 during expert discovery in accordance with the Court's Scheduling Order. (*See id*.). Defendant never filed a motion to compel on that issue. *See, e.g., U.S. v. Certain Real Prop. Located at Route 1, Bryant, Ala.*, 126 F.3d 1314 (11th Cir. 1997) (reversing an order imposing sanctions when there was no prior order compelling the production of the discovery at issue and no prior motion to compel was filed); *Fujifilm Corp. v. Motorola Mobility LLC*, No. 12-CV-03587-WHO, 2015 WL 757575, at *29 (N.D. Cal. Feb. 20, 2015) (denying motion to exclude defendant's expert report where plaintiff did not first file a motion to compel). Defendant and Dr. Lowman understood that Wallace teaches that the specific hydrogels of Rhee '500 create "severe foreign body response," "severe inflammation," and "thick encapsulation of the hydrogel and abscess formation." Dr. Lowman even cited these experimental results from Wallace in his opening expert report. (*See* Ex. 4 at ¶¶508-520.) Plaintiffs' experts timely and appropriately rebutted Dr. Lowman's prior art invalidity positions by opining that one of skill would understand, based on Wallace, that the very hydrogels of Rhee '500 relied on by Dr. Lowman were tested by Dr. Rhee (an inventor in Wallace) and were determined to be not biocompatible. The requirement of biocompatibility of the claims of the patents-in-suit was not unknown to Defendant or to Dr. Lowman as Defendant asserted the invalidity of every claim where biocompatibility was mentioned in Defendant's Final Invalidity Contentions. Biocompatibility was squarely an issue. Yet pursuant to a well-informed litigation strategy, Defendant and Dr. Lowman selected Rhee '500 and Wallace to assert invalidity. In rebuttal, Dr. Mays, Dr. Rivet, and Dr. Distefano used only the evidence in Dr. Lowman's opening expert report to opine that the selected art failed to teach or suggest the claimed biocompatible hydrogels. It is simply not credible that Defendant's counsel and Dr. Lowman were unaware of the determination by Dr. Rhee that the hydrogels relied on by Dr. Lowman were not biocompatible. However, in view of such damaging rebuttal striking at the very heart of Dr. Lowman's prior art invalidity positions using evidence presented in his own expert report, Defendant filed the baseless motion to strike. As with the priority information, it is not credible that both Dr. Lowman and Defendant's many litigation counsels, again, simply and stubbornly put their heads in the sand with respect to the teachings of Wallace that the hydrogels are not biocompatible, while contending that every claim including the term was invalid.

It is well-recognized that expert opinions are not required to be disclosed before the deadline for serving expert reports, and that expert reports serve to supplement interrogatory responses. The opinions of Dr. Mays, Dr. Rivet, and Dr. Distefano regarding priority and biocompatibility were in direct response to Dr. Lowman's opening expert report alleging prior art invalidity of the Asserted Claims and are therefore timely and proper. *See Beneficial Innovations, Inc. v. AOL LLC*, Case No. 2:07-cv-555, Dkt. No. 260 at 1 (E.D. Tex. May 26, 2010) (a party is "not required [ ] to disclose its experts' opinions in advance of the deadline for serving expert reports.") (Ex. 5); *id.* at Dkt. No. 256 (Ex. 6); *IP Innovation L.L.C. v. Sharp Corp.*, 219 F.R.D. 427, 430 (N.D. Ill. 2003); *Duncan v. Chevron U.S.A., Inc.*, No. CIV.A. 10-0298, 2011 WL 2457652, at *2-3 (E.D. La. June 16, 2 011); *see also Marical Inc. v. Cooke Aquaculture Inc.*, No. 1:14-CV-00366-JDL, 2017 WL 3812866, at *3 (D. Me. Aug. 31, 2017) (denying parties' respective motions to strike expert opinions because the opinions themselves constitute a proper supplementation of the interrogatory responses and constitute "the continued

development and modification of the expert's assessment" and party contentions due to the natural evolution of these with the information generated in discovery and that any prejudice can be addressed in reply expert reports); *Baltimore Aircoil Company, Inc. v. SPX Cooling Technologies, Inc.*, No. CV CCB-13-2053, 2016 WL 4426681, at *21-22 (D. Md. Aug. 22, 2016) (finding that deposition testimony was sufficient to supplement response to interrogatory).

Defendant's argument regarding an alleged violation Fed. R. Civ. P. 26 and 37 is misplaced. Fed. R. Civ. P. 26(e)(1) states that the supplementation or correction must "in a timely manner if the party learns that in some material aspect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been known to the other parties during the discovery process or in writing;" (emphasis added). Here, all of the factual information relied on by Plaintiffs' experts to rebut the prior art invalidity positions was already known to Defendant and Dr. Lowman. The asserted priority dates and priority documents, as well as inventor witnesses, were provided to Defendant. Defendant and Dr. Lowman had every opportunity to investigate Plaintiffs' asserted priority dates. Wallace was also identified by Defendant in its Initial Invalidity Contentions. (*See* Ex. 7 at 23 and 28). As discussed above, the teaching of Wallace that the hydrogels described in the Rhee '500 caused a "severe foreign body response," "severe inflammation," and "thick encapsulation of the hydrogel and abscess formation" during *in vivo* testing was specifically cited by Dr. Lowman in his opening expert report. (*See* Ex. 4 at ¶¶508-520). In direct rebuttal, Dr. Rivet, Dr. Mays, and Dr. Distefano opined that the "biocompatibility" testing disclosed in the Wallace '725 patent directly refutes Dr. Lowman's invalidity contentions. Dr. Lowman responded at length to Dr. Rivet's, Dr. Mays', and Dr. Distefano's opinions regarding the "biocompatibility" testing of the Wallace '725 patent in his reply report. (*See* Ex. 8 at ¶¶22-80). Additionally, Defendant's counsel questioned Dr. Mays and Dr. Rivet (Dr. Distefano is scheduled for deposition on November 8, 2017) about their opinions regarding the "biocompatibility" testing of the Wallace '725 patent at their respective depositions. Ex. 9 at 319-349; Ex. 10 at 330-349.

Defendant's reliance on *Walker Digital, LLC v. Google Inc.* is also misplaced. *Walker Digital* is readily distinguishable. In *Walker Digital*, this Court stated, "Walker Digital chose to present its infringement allegations in a conclusory fashion in its expert report and did not provide an infringement chart." *Walker Digital, LLC v. Google Inc.*, C.A. No. 11-309-SLR, 2013 WL 2949109, at *2 (D. Del. June 14, 2013) (emphasis added). Dr. Mays, Dr. Rivet, and Dr. Distefano did not raise new and conclusory infringement theories in rebuttal. Instead, they responded to Dr. Lowman's prior art invalidity positions using the very same fact discovery available to Defendant. Further, Dr. Lowman had full opportunity respond to Dr. Mays', Dr. Rivet's, and Dr. Distefano's opinions in his reply report. (*See* Ex. 8 at ¶¶22-80.) Defendant also had the opportunity to depose Plaintiffs' experts regarding the biocompatibility issues. Further, *Walker Digital* does not stand for the broad exclusionary rule Defendant suggests, which is clear from the legion of cases from this district refusing to strike opinions related to key issues like validity of the patents-in-suit.[1]

[1] *See, e.g., EMC Corp. v. Pure Storage, Inc.*, 154 F. Supp. 3d 81, 102-103 ("The *Penypack* factors militate against striking the Li and Jestice declarations and exhibits thereto."); *Masimo*

**_Pennypack_ Factors**

Even assuming, *arguendo*, that the Court considers the evidence supporting the asserted priority dates and biocompatibility opinions to be untimely, the *Pennypack* factors weigh against striking such evidence.

- **Factor 1 –** There is no surprise or prejudice. Defendant has known for nearly a year the priority dates of the asserted claims that the Plaintiffs intended to rely upon. *See Dynamic Digital Depth Research Pty Ltd. v. LG Elecs., Inc.*, No. CV 15-5578-GW(EX), 2016 WL 7448294, at *5 (C.D. Cal. June 7, 2016) (holding accused infringer "not materially prejudiced" and denying request to strike as untimely the plaintiff's disclosure of a new priority date five months prior to final invalidity contention deadline). With respect to the rebuttal reports of Dr. Mays, Dr. Rivet, and Dr. Distefano, Defendant has had ample time to refute their "biocompatibility" opinions via Dr. Lowman's reply report. (*See* Ex. 8 at ¶¶22-80). Further, Defendant had the opportunity to depose all experts on topics related to their biocompatibility opinions. (Ex. 9 at 319-349; Ex. 10 at 330-349).

- **Factor 2 and 3** – Since there is no prejudice, no "cure" is needed and no delay in trial is warranted as Defendant's expert has already provided his rebuttal opinion, and Defendant has deposed all of the Plaintiffs' experts. (*See* Ex. 8 at ¶¶22-80; Ex. 9 at 319-349; Ex. 10 at 330-349).

- **Factor 4 – No "Bad Faith" or "Willful Disregard"** – This court has reserved findings of "bad faith" or "willful disregard" to clear, extreme examples of such conduct. *Withrow v. Spears et al.*, 967 F. Supp. 2d 982, 1006 (D. Del. 2013) (citing examples such as filing an expert report 3½ years after the deadline with no justification; failure to seek leave of court before filing untimely expert report); *see also* DeMarines *v. KLM Royal Dutch Airlines*, 580 F.2d 1193, 1202 (3d Cir. 1978) (reversing district court's exclusion of witness when there was only slight prejudice to the defendant as they were already aware of the basic substance of the witness's testimony). Here, there was no "bad faith"

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*Corp. v. Philips Elec. N. Am. Corp.*, 62 F. Supp. 3d 368, 383 (D. Del. 2014) ("In sum, consideration of the *Pennypack* factors leads to the conclusion that striking Masimo's opposition to treating Ukawa as prior art is not warranted."); *Lambda Optical Sols., LLC v. Alcatel-Lucent USA Inc.*, C.A. No. 10-487-RGA, 2013 WL 1776104, at *9 (D. Del. Apr. 17, 2013), *report and recommendation adopted*, 2013 WL 12156799 (D. Del. May 13, 2013) ("[A]ll or nearly all of the *Pennypack* factors militate in favor of a conclusion that, even if Alcatel did fail to timely disclose information responsive to the interrogatory at issue, such failure was harmless and was substantially justified under the meaning of the law."); *Intermec Techs. Corp. v. Palm Inc.*, C.A. No. 07-272-SLR, 2010 WL 2340228, at *2 (D. Del. June 7, 2010) ("In considering these factors, the court finds that exclusion of the Trakker disclosures would be an extreme and unwarranted sanction in this case.").

or "willful disregard" as to the priority dates of the asserted claims, or the expert opinions related to biocompatibility.

- **Factor 5 – Explanation for the failure to disclose** – Again, Plaintiffs' position is that there was no failure to disclose the asserted priority dates and Plaintiffs met their burden of producing supporting evidence. In addition, Plaintiffs' expert biocompatibility opinions are just that—the experts' **individual** opinions in direct response to the opinions presented by the Defendant's expert report. Defendant's reliance on *Tyco Healthcare* misleads the Court. Like *Walker Digital*, this case is readily distinguishable: the Federal Circuit held that this Court did not abuse its discretion in precluding patentee from presenting evidence regarding a new *infringement* theory not properly raised during discovery. *Becton, Dickinson & Co. v. Tyco Healthcare Grp.*, 616 F.3d 1249, 1261 (Fed. Cir. 2010).

- **Factor 6 – Importance of Evidence to Plaintiffs** – The evidence sought to be excluded is of significant importance to Plaintiffs as it is goes to the validity of the asserted claims. *Praxair, Inc. v. ATMI, Inc.*, 231 F.R.D. 457, 463 (D. Del. 2005), *rev'd on other grounds*, 543 F.3d 1306 (Fed. Cir. 2008) ("the exclusion of otherwise admissible testimony because of a party's failure to meet a timing requirement is a harsh measure and should be avoided where possible"); *see also Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 905 (3d Cir.1977) ("[T]he exclusion of critical evidence is an 'extreme' sanction . . . not normally to be imposed absent a showing of willful deception or 'flagrant disregard' of a court order by the proponent of the evidence."); *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1573 (Fed. Cir. 1985) ("Before rendering its judgment, the court must determine whether '*all* of the evidence establishes that the validity challenger so carried his burden as to have persuaded the decision maker that the patent can no longer be accepted as valid.'") (quoting *Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F.2d 881, 885 (Fed. Cir. 1984)).

For all of these reasons, the Court should deny "Defendant's Motion to Strike Plaintiffs' New Identification of Evidence Regarding Priority Dates and New Biocompatibility Theory" [D.I. 375].

Respectfully submitted,
*/s/ Karen L. Pascale*
Karen L. Pascale (No. 2903)

cc: Counsel of Record (By CM/ECF and E-mail)